



DEPUTY
ADMINISTRATOR

DEPARTMENT OF THE TREASURY
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU
WASHINGTON, DC 20226

JUL -3 2003

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Mr. Nega Beru
Center for Food Safety and Applied Nutrition (HFS-305)
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

Re: Docket No. 02N-0277
Establishment and Maintenance of Records under the Public
Health Security and Bioterrorism Preparedness and Response Act of
2002

Dear Mr. Beru:

The Alcohol and Tobacco Tax and Trade Bureau (TTB) submits this comment in response to the above-referenced notice of proposed rulemaking recently published by the Food and Drug Administration (FDA). The proposed rule implements provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), legislation directed at protecting the safety and security of the nation's food supply. For purposes of the Bioterrorism Act, the term "food" includes alcohol beverages.

TTB regulates the alcohol beverage industry and administers the licensing, labeling, taxation, trade practice, and related recordkeeping requirements imposed upon the industry by Federal law. By letter dated April 4, 2003, TTB submitted comments on the first two notices of proposed rulemaking published by FDA to implement the Bioterrorism Act. TTB continues to stand ready to assist and collaborate with FDA in implementing the Bioterrorism Act in a manner that avoids duplication of efforts and undue burden on the alcohol beverage industry.

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Mr. Nega Beru

Proposed Recordkeeping Requirements

The proposed rule implements the Bioterrorism Act by requiring the establishment and maintenance of records by certain domestic persons who manufacture, process, pack, transport, distribute, receive, hold, or import food intended for human or animal consumption in the United States. The requirements also apply to certain foreign facilities that manufacture, process, pack, or hold food intended for human or animal consumption in the United States.

The records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. In section 306(d) of the Bioterrorism Act, the Secretary of Health and Human Services was directed to issue proposed and final regulations establishing recordkeeping requirements by December 12, 2003. The Bioterrorism Act also amended the Federal Food, Drug, and Cosmetic Act to make it a prohibited act to refuse to permit access to, or copying of, any required record, or to fail to establish or maintain any required record.

FDA's proposed regulations set forth the specific information that a covered entity must keep, but do not specify the form or type of system in which those records must be maintained. The proposed rule provides that, to the extent that a covered entity keeps records of all the required information in compliance with other Federal, State, or local regulations, these records may be used to satisfy the proposed requirements. Commercial records such as purchase orders, bills of lading, invoices, and shipping documents may also be used to satisfy the proposed requirements.

TTB supports the proposed flexibility to use existing records to meet the requirements of the Bioterrorism Act. This flexibility would allow alcohol beverage industry members to utilize records required under the requirements of Federal, State, or local regulations to satisfy the recordkeeping requirements of FDA's proposed regulations. In addition, an industry member may use commercial records to satisfy these requirements. Thus, for example, an alcohol beverage producer may be able to utilize records required under the Internal Revenue Code of 1986, supplemented by commercial records, to satisfy FDA's proposed recordkeeping requirements, without having to create an entirely new system of records to satisfy FDA's requirements. TTB believes that this element of the proposed regulation will minimize the recordkeeping burdens imposed on alcohol beverage industry members, while still providing FDA with the important information needed to effectively implement the requirements of the Bioterrorism Act.

Mr. Nega Beru

Conclusion

Thank you for allowing TTB the opportunity to comment on FDA's proposed regulations. TTB recognizes the importance of FDA's statutory mission to protect the integrity of the nation's food supply. We stand ready to assist FDA in any way possible.

Sincerely yours,

A handwritten signature in black ink, reading "John J. Manfreda". The signature is written in a cursive style with a large, stylized "J" and "M".

John J. Manfreda
Deputy Administrator